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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,477

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EXAMINER

KATAKAM, SUDHAKAR

ART UNIT

PAPER NUMBER

1621

NOTIFICATION DATE

DELIVERY MODE

02/08/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/574,477	<b>Applicant(s)</b> SUDOH ET AL.	
	<b>Examiner</b> SUDHAKAR KATAKAM	<b>Art Unit</b> 1621	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,7,8,12-14,16,18,19,27-31 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) 18,19 and 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7,8,12-14,16, 27, 28 and 33-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/1/10,12/30/10</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Status of the application***

1. Receipt of Applicant's Remarks and Arguments filed on 29 Nov 2010 is acknowledged. However, the arguments for the 103(a) rejection are not found persuasive and as such, the previous rejection has been maintained for the reasons of record made on made on 29 June 2010.

### ***Response to Arguments***

2. Applicant's arguments filed on 29 Nov 2010 have been fully considered but they are not persuasive.

*(i) Applicants argue that the examiner's position is based primarily on improper hindsight reconstruction and the examiner has not provided a reasonable technical basis for asserting that, even if the references could be combined, a micelle water dispersion would be obtained.*

Formation micelle water dispersion is concentration dependent. Applicants' compound has hydrophobic head (alkyl chain) and hydrophilic tail (carboxylic acid). Applicants' compound is expected to form a micelle water dispersion based on the concentration of components in the composition. The purpose of combined references in the office action to show applicants compound and its possible salts.

*(ii) Applicants argue that the examiner relies on 6 different references, none of which teach the combination of the claimed (2R)-2-propyloctanoic acid or salt thereof and a basic metal ion supplied by at least one selected from a metal salt of phosphoric*

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acid, a metal salt of carbonic acid and a metal salt of sulfuronic acid, much less having about 1 to 5 equivalents of a basic metal ion based on 1 equivalent of (2R)-2-propyloctanoic acid or salt thereof.

Number of references based on the limitations in the claim language. The purpose of several references is to show the established art for applicants' composition. The primary reference (**Hasegawa et al** or **JP 8291106**) teach applicants compound and its salt form for the treatment of neurodegenerative diseases. The secondary references showed salt of applicants' compound, for example sodium salt and also adjusting the pH of medium with buffer. The amount of salt or basic metal ion is a result effective variable for the composition and therefore it is considered as an optimizable parameter. The a skilled person can expect the effects of using too little or too much salt or basic metal ion for the composition and one of skill in the art would know to optimize the amount of salt to avoid undesirable effects.

(iii) Applicants argue that the present invention provides unexpectedly superior results over the prior art.

Applicants filed declaration reveals that (a) applicants compound in the acid form is not soluble in water, and can be dissolved in water in high concentration in their medicament, (b) the medicament has resistance to pH fluctuations, (c) it is possible to prepare an infusion, which has a pH that can be administered to patients without clouding.

With regard to (a) of above, the acid form of applicants compound is insoluble in water, which is already known in the art. However, it is soluble in water in high concentration in applicants' medicament, because the compound exists in salt form, which is exactly one would expect a pharmaceutical compound in the salt form.

With regard to (b) of above, the resistance to pH fluctuations depend on the salt concentration or buffer concentration. A skilled person can expect the effects of using too little or too much salt or basic metal ion for the composition and one of skill in the art would know to optimize the amount of salt to avoid undesirable effects.

With regard to (c) of above, yes it is possible to avoid clouding of a compound using a proper buffering conditions for the drug. A skilled person in the art can determined these factors through a routine experimentation.

(v) Applicants argue that the equivalent number of basic metal ion, which is essential feature of claims in the present invention, is not disclosed in either of Takeda et al or Honjo et al.

The amount of salt or basic metal ion is a result effective variable for the composition and therefore it is considered as an optimizable parameter. A skilled person can expect the effects of using too little or too much salt or basic metal ion for the composition and one of skill in the art would know to optimize the amount of salt to avoid undesirable effects. The cited prior art does not explicitly disclose the amount of metal ion or salt, because it is well known fact in the art and skilled person always chooses suitable concentration range to avoid undesirable effects.

*(vi) Applicants argue that in **Nakaoka et al**, wherein the mixing ratio of aliphatic monocarboxylic acids and inorganic metal salts is disclosed, a far less equivalent number is described in comparison to the present invention.*

The purpose of **Nakaoka et al** is to show use of inorganic metal salt for aliphatic monocarboxylic acid, because applicants' compound is also an aliphatic monocarboxylic acid. **Nakaoka et al** teach an aliphatic monocarboxylic acid composition, composed of one or more kinds of aliphatic monocarboxylic acids of formula R-COOH (R is a 5-21C straight or branched-chain alkyl or alkenyl) in combination with one or more kinds of inorganic salts selected from metal phosphates, metal phosphinates and metal sulfites. The inorganic metal salt is preferably one or more compounds selected from alkali metal phosphates and alkaline earth metal phosphates. Again the concentration of inorganic metal salt is optimizable parameter and its amount depends on the conditions of the composition. One of skill in the art would know to optimize the amount of metal salt to avoid side effects in the resulted composition.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 7, 8, 12-14, 16, 27, 28, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hasegawa et al** (Bull.Chem.Soc.Jpn. 2000, 73, 423-428) or **JP 8291106** in view of **Ohuchida et al** (US 6,201,021), **Black** (US 6,043,223), **Toda et al** (US 6,608,221) and **Takada et al** (US 2002/0022738 A1).

6. Claims 1, 7, 8, 12-14, 16, 27, 28, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Honjo et al** (EP 1 415 668 A1) in view of **Nakaoka et al** (JP 07285911 A) and **Takada et al** (US 2002/0022738 A1).

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136 (a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no even, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Conclusion***

8. No claim is allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/  
Primary Examiner, Art Unit 1621